No. 94-372

In the Supreme Court of the United States

OCTOBER TERM, 1994

DONNA E. SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, PETITIONER

v.

MARGARET WHITECOTTON, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FEDERAL CIRCUIT

REPLY BRIEF FOR THE PETITIONER

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TABLE OF AUTHORITIES

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1. We have argued in our petition (Pet. 12-15) that the court of appeals erred in holding that the National Childhood Vaccine Injury Act of 1986, 42 U.S.C. 300aa-1 *et seq.*, creates a presumption that a vaccine has caused a compensable injury any time that a child with a pre-existing condition experiences an additional symptom or manifestation of that condition during the statutory period. The text of the Act unambiguously limits compensation in such circumstances to cases in which the child's preexisting condition was "significantly aggravated" during the statutory period, 42 U.S.C. 300aa-11(c)(1)(C)(i)—a showing that was not made here. See Pet. 8-9, 13.

Respondents offer no defense of the court of appeals' interpretation of the Vaccine Act. Instead, they seek to defend the judgment on another ground. Respondents assert (Br. in Opp. 12-19) that Maggie Whitecotton did not have clinically significant microcephaly before she took her third DPT vaccine, and that the seizures she suffered after the vaccination were therefore the first manifestations of her encephalopathy. That assertion ignores the special master's findings, which were affirmed by the Court of Federal Claims and were not disturbed by the court of appeals.

Based on the sources cited by the parties at the hearing on respondents' claim, as well as one additional source previously relied upon by the Court of Federal Claims, the special master adopted what he found "to be the most commonly accepted definition of microcephaly, namely, a head size smaller than two standard deviations below the mean for a child of the same sex and age." Pet. App. 32a. Applying that definition, the special master found that Maggie was "at least borderline microcephalic at birth and that she was clearly microcephalic by the time she received her third DPT shot on August 18, 1975." *Id.* at 32a-33a. The special master's finding was supported not only by evidence offered by the government, but also by respondents' own expert, who testified that "[s]omething was clearly happening to the child before [the DPT shot]." *Id.* at 33a. In his report, respondents' expert elaborated that the growth of Maggie's head had fallen below the normal curve, which "implie[d] a post-partum injury to the brain, at or near three months of age." *Id.* at 34a. The administration of the DPT vaccine that respondents allege as the cause of Maggie's condition occurred later, almost four months after she was born. *Id.* at 11a. In light of that evidence, the special master reasonably found that "[w]hether the

injury occurred prior to birth or thereafter, the preponderance of evidence indicates that Maggie was already encephalopathic prior to August 18, 1975." *Id.* at 34a.*

The court of appeals did not expressly affirm the special master's finding that Maggie was microcephalic before her third DPT vaccination. Pet. App. 8a. But neither did it disturb that finding. To the contrary, the court of appeals acknowledged that "[l]ogically, [the special master's findings] point to some preexisting condition, and not the vaccine, as the source of Maggie's injury." *Ibid.* The court of appeals held, however, that the special master's findings were irrelevant in deciding whether Maggie had suffered a Table encephalopathy. In the court's view, to benefit from the statutory presumption of causation, the claimant need only show that a symptom of an encephalopathy happened to occur during the Table period, not that the *first* such symptom occurred during that period. *Id.* at 5a. It is that legal holding we challenge in our petition.

The United States has not sought to deprive respondents of the opportunity to present arguments to the court of appeals on the factual issues of whether Maggie was clinically microcephalic before taking the vaccine and whether her preexisting condition was significantly aggravated during the Table period. What the United

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* In affirming the special master's finding, the Court of Federal Claims rejected respondents' contention that the special master had arbitrarily adopted the strictest definition of microcephaly. Pet. App. 20a. The court noted that "[e]ach of the experts that testified in this case acknowledged that this definition was accepted by the medical profession." *Ibid.* The court of appeals did not overturn that factual finding. Respondents' objection to that finding (Br. in Opp. 12-19) is without merit, and it does not in any event furnish a basis to deny review of the court of appeals' erroneous legal rulings.

States objects to is the court of appeals' conclusion that it is no longer necessary to resolve factual questions like that to decide whether a child is entitled to compensation. The court's holding that a child is presumptively entitled to compensation upon proof that a symptom or manifestation of a Table condition happened to occur within the Table period, without regard to whether the child was already suffering from such a condition, reflects a serious misinterpretation of the Vaccine Act.

2. As we have argued in the certiorari petition (Pet. 17-19), the court of appeals compounded its error by holding that the government could not rely on Maggie's microcephaly to rebut a prima facie case of causation. Pet. App. 7a-8a. The Vaccine Act permits the government to rely on "factors unrelated" to the vaccine to rebut a prima facie case. 42 U.S.C. 300aa-13(a)(1)(B). And while the statute precludes reliance on "idiopathic" factors, 42 U.S.C. 300aa-13(a)(2)(A), Maggie's microcephaly is not idiopathic, since it is a defined preexisting condition that logically eliminates the vaccine as the cause of her condition. See Pet. 17-19.

Rather than defending the court of appeals' reasoning, respondents offer an even more restrictive view of what constitutes a permissible rebuttal of a prima facie case. Respondents contend (Br. in Opp. 19) that "factors unrelated" to the vaccine are limited to "toxins, trauma, infection or metabolic disturbance." Since Maggie's microcephaly cannot be traced to one of those four factors, respondents argue, the government failed to establish that a factor unrelated to the vaccine caused Maggie's condition. Respondents' contention is without merit.

Section 300aa-13(a)(2)(B) provides that factors unrelated to the vaccine "may * * * include infection,

toxins, trauma (including birth trauma and related anoxia), or metabolic disturbances which have no known relation to the vaccine involved, but which in the particular case are shown to have been the agent or agents principally responsible for causing the petitioner's illness, disability, injury, condition, or death." 42 U.S.C. 300aa-13(a)(2)(B). The words "may include" indicate that Congress intended that the four identified factors be treated as examples of permissible rebuttal, rather than as an exhaustive list.

Respondents appear to concede that point, but then contend (Br. in Opp. 21-22) that the permissive language of that provision is overridden by Section 300aa-14(b)(3)(B), which relates to encephalopathies. That section provides that "[i]f * * * an encephalopathy was caused by infection, toxins, trauma, or metabolic disturbances the encephalopathy shall not be considered to be a condition set forth in the table." 42 U.S.C. 300aa-14(b)(3)(B). That language, however, simply mirrors the text of Section 300aa-13(a)(2)(B). Nothing in that language compels the conclusion that the four listed factors were intended to be the only factors that could defeat a finding of a Table encephalopathy.

Respondents argue (Br. in Opp. 20-21) that the use of the word "shall" suggests that the four factors are exclusive rather than illustrative. But the term "shall" simply indicates that if the government proves that one of the four listed factors caused the child's injury, the court must deny compensation. It does not suggest that if the government proves that a different factor caused the encephalopathy, the court must ignore the force of that evidence. Moreover, the second sentence of Section 300aa-14(b)(3)(B) confirms that the first sentence was not intended to limit rebuttal to the four identified factors. The second sentence provides that "[i]f at the

time a judgment is entered * * * it is not possible to determine the cause, by a preponderance of the evidence, of an encephalopathy, the encephalopathy shall be considered to be a condition set forth in the table." If respondents' construction of the first sentence were correct, the second sentence would have provided that "if an encephalopathy is not shown by a preponderance of the evidence to have been caused by infection, toxins, trauma, or metabolic disturbances, the encephalopathy shall be considered to be a condition set forth in the table." The quite different and more limited scope of the second sentence makes clear that the government can rely on a factor that is not one of the listed four, as long as it is possible to determine by a preponderance of the evidence that the factor identified by the government caused the encephalopathy.

Respondents' more restrictive interpretation makes no sense. If respondents' view were accepted, it would mean that, for no apparent reason, Congress adopted a different standard of rebuttal for encephalopathies than for all other Table conditions. Even more significantly, it would mean that in cases involving encephalopathies, the Secretary would be unable to rely on genetic conditions, such as Down's syndrome, to rebut a prima facie case. Congress could not have intended that result.

3. Finally, respondents erroneously contend (Br. in Opp. 11) that our concerns about the financial implications of the court of appeals' decision are artificial. As we have explained (Pet. 19-20), the court of appeals' decision, if allowed to stand, would immediately threaten the fiscal integrity of the fund for retrospective cases and could readily require $200 million in additional (and erroneous) compensation awards over the next ten years.

CONCLUSION

For the foregoing reasons and those stated in the petition, the petition for a writ of certiorari should be granted.

Respectfully submitted.

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